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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,239	03/23/2004	Rosario Lizio	104085-393-CON	5035
24964 7590 02/07/2007 GOODWIN PROCTER L.L.P. 599 LEXINGTON AVE. NEW YORK, NY 10022			EXAMINER AUDET, MAURY A	
			ART UNIT 1654	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		02/07/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/808,239

Applicant(s)

LIZIO ET AL.

Examiner

Maury Audet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/11/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-13 and 15-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept.

In accordance with 37 CFR 1.142, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-8 and 20-23, drawn to a process for preparing a fine particulate protein substance or substance mixture comprising any single suspending medium OR mixture thereof and any single excipient OR mixture thereof; classified in class 424, subclass 1.69+.
- II. Claims 9-12, drawn to a solid, fine-particulate pharmaceutical preparation for inhalatory administration to mammals comprising a fine particulate protein substance or substance mixture comprising any single suspending medium OR mixture thereof and any single excipient OR mixture thereof; classified in class 514, subclass 20+.
- III. Claims 13, 15-19 and 24, drawn to a process for applying a fine-particulate substance OR substance mixture preparing a fine particulate protein substance or substance mixture comprising any single suspending medium or mixture thereof and any single excipient or mixture thereof; classified in class 424, subclass 1.69+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be

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used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed can be used to make another and materially different product, namely any independent and distinct protein substances OR mixtures, each of which may be entirely distinct.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed can be practiced with any independent and distinct protein substances OR mixtures, each of which may be entirely distinct.

Inventions I and III are directed to different methods of use, which are not connected in design, operation, and/or effect. These methods are independent since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference, which would anticipate the invention of one group, would not necessarily anticipate or even make obvious another group.

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Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Restriction for examination purposes is therefore proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not necessarily required for Group II, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Irrespective of which Group is elected as the invention, the following is further required:

A. Requirement for a Single Suspending Medium or Suspending Medium Mixture Election

Absent evidence to the contrary that ANY single suspending medium OR suspending medium mixture (see open claim 1) may be used to carry out the invention and that any art found upon any single suspending medium or suspending medium mixture would in turn render obvious any other single suspending medium or suspending medium mixture, Applicant is required to elect, as the invention, either a single suspending medium (e.g. TG227) or a specific suspending medium mixture (e.g. TG227 and butane). Under a reasonable interpretation of the claim language (e.g. claim 1), one of ordinary skill in the art would have a reasonable expectation of success that any suspending medium or mixture thereof would carry out the invention. A search of any and all potential single suspending mediums OR suspending medium

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mixtures, assumed to be distinct inventions with the other potential elements of the invention, is not coextensive nor are any and all single mediums/mixtures members of an art recognized Markush group – thus posing an undue search burden; again absent evidence to the contrary that any single medium/mixture found in the art with the other element(s) of the invention renders any other single medium/mixture obvious. **This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each compound or mixture is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.**

B. Requirement for a Single Excipient or Excipient Mixture Election

The claimed excipients of claim 7 are not members of any recognizable Markush group (e.g. entirely unrelated lactose v. vitamins), therefore they are not species of any genus. [This is not withstanding the uncertainty of whether these excipients are even required as essential to carry out the invention, as there is no mention of them until dependent claim 7]. Absent evidence to the contrary that virtually any excipient (e.g. lactose) or excipient mixture (e.g. lactose and vitamins) may be used to carry out the invention, and that any art found upon any single excipient or excipient mixture would in turn render obvious any other single excipient or excipient mixture, Applicant is required to elect, as the invention, either a single excipient or a specific excipient mixture. A search of virtually any excipient or mixtures thereof (unless Applicant admits on record that any excipient can carry out the invention and that any said excipient is not essential to carry out the invention), assumed to be distinct inventions with the other potential elements of the invention, is not coextensive nor said excipients/mixtures members of an art recognized Markush group – thus posing an undue search burden; again

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absent evidence to the contrary that any single excipient/mixture found in the art with the other element(s) of the invention would render obvious any other single excipient/mixture. **This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each compound or mixture is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.**

Species Election Alternative

This application contains claims directed to the following patentably distinct species of the claimed invention: protein substance or protein substance mixture. It is assumed that any protein substance or protein substance mixture (that may be inhaled in the context of Group II) can be used in the invention. Applicant is required to elect a single protein substance or protein substance mixture (e.g. abarelix), as to the elected invention.

Alternative to B. above, this application may be amended and then viewed to contain claims directed to the following patentably distinct species of the claimed invention. Should Applicant amend claim 1 to be drawn to a distinct, art recognized Markush group for a SINGLE suspending medium (not mixtures, as mixtures do not fall in the category of a Markush group, based on unique properties (e.g. synergistic)/distinct searches thereto), the Examiner is willing to have Applicant elect a single SPECIES (e.g. butane) from one of said Markush group. [The same option has not been extended to the excipients as such are merely listed in later claim 7, and are not deemed essential to the invention, similar to an additive that can be put in if desired by routine optimization by the skilled artisan]. For example claim 1, line 7 could be amended to "...suspending medium selected from the group consisting of butane, isobutene, ..." OR

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“...suspending medium selected from the group consisting of TG227, TG134a, ...” [if the TG’s are not compounds falling within an art recognized Markush group with the likes of e.g. butane] - and listing those compounds falling within said Markush group of suspending agents having a reasonable expectation of success of carrying out the invention, based on specification support via testing or evidence known in the art of the properties/capabilities of said suspending agents in the context of this invention.

The species are independent or distinct because a search for any of the above species is not necessarily co-extensive particularly with regard to the literature search and a reference, which would anticipate any one of the above species, would not necessarily anticipate or even make obvious another species, absent evidence to the contrary.

Applicant is required under 35 U.S.C. section 121 to elect a single disclosed species above (e.g. abarelix and, if appropriate as to the alternative to B., e.g. butane) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 1, 9, and 13 are generic.

Applicant is advised that a reply to this requirement must include an identification of the elected species consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations

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of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. MPEP section 809.02(a).

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. section 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

In re Ochiqi/Brouwer Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.

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See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Appropriate Amendment of the Claims

In the interests of compact prosecution and to hasten examination on the merits, Applicant is asked to amend the claims commensurate in scope with the elections made in response hereto.

It is noted there is no antecedent basis in claim 10 for "active compound". Claim 9 only discusses "protein substance". Appropriate correction is requested before prosecution on the merits.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

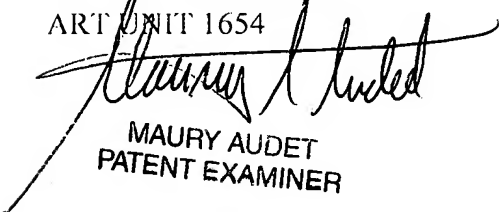
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 1/11/2006

MAURY AUDET
PATENT EXAMINER
ART UNIT 1654



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PATENT EXAMINER